Division of Ethicon, Inc.

Technical Bulletin Number: TB	116099	Date: 4/	26/02
Technical Bulletin Category:	Mandator Mandator As Requi	ry Next Call	
<u>Technical</u> Bulletin Title: LFPS2	Retrofit Ki terilizers	t for STERRAI	D <sup>®</sup> 100S
Product(s) Covered:1005010200  Originator, If this bulletin is Mandatory or M	10217	2030X	

Part Numbers: 05-50559-0-002

Technical Specialist: Tim Weidinger Phone: 949 789-3872

# **CO Reference:**

Approvals-Must Be Hand Signed						
Originator	Date	Tech. Support		Date	Field Service	Date
Tim Weidinger	4/25/02	N/A		4/25/02	Tom Kijanka	4/25/02
Depot	Date	Distrib	ution	Date	Regulatory	Date
Atam Singh	4/26/02	Gil Gamez		4/25/02	Kevin Corrigan	4/26/02
R&D	Date	Other		Date	Other	Date
John Chen	4/25/02					
Released	Internet	t Email	File	Fax?		
Rebecca Tappy	4/25/02	4/25/02	4/25/02	Yes 🗌		
				No ⊠		

# **Special Tools Required**

- BNC-to-banana plug cable.
- IEC320 power cord (used on Bird Wattmeter.)
- LFPS2 Power Verification Meter (35-50384-0-001).
- Electrostatic Discharge Mat w/wrist grounding strap
- Service Access Key (04-09071-0-001)
- Service Access Key Autotest Guide (TS-50026-0-002)

### **Problem**

RF generators are no longer supplied for STERRAD® 100S Sterilizer systems.

## Solution

For STERRAD 100S Sterilizer systems, the RF generator is replaced by the LFPS2 (Low Frequency Plasma System) at the next RF related failure. Additionally, the RF match box is no longer required and is replaced by a feed through box. The firmware released on TB115999 (Mandatory, Next Call) will automatically detect and control the LFPS2.

Verify the minimum firmware version is 04-05526-6-601 for US domestic systems or 04-05524-3-6XX for international systems. If the firmware is an earlier version, update the firmware per TB115999.

#### Reference

- TS-02859-0-002 Rev. D Service Guide
- TS-50026-0-002 Service Access Key Autotest Guide
- TB115999 Technical Bulletin, Mandatory Next Call, Firmware Upgrade

### **Procedure**

#### LFPS2 Installation

- 1. Turn off power to the sterilizer and remove all the panels. Refer to the STERRAD 100/100S Service Guide for specific instructions.
- 2. Remove the RF generator. Save the mounting hardware for reuse.
- 3. Remove the RF coaxial cable.

- 4. Remove the RF match assembly and the mounting hardware. Save the feed through mounting screw for reuse.
- 5. Remove the punch-out on the feed through box (31-50145-0-001) and install the feed through box where the RF match was located using a lock washer and a 3/8" NPT brass conduit nut. Orient the box so that the connector is facing the right side of the sterilizer, as viewed from the front. Tighten securely. Position a second a 3/8" NPT brass conduit nut 0.5 ~ 1.0 mm from the first nut. Insert the ground lug from the feed through box into the feed through fitting. Insert a lock washer into the feed through fitting. Insert another 3/8" NPT brass conduit nut to complete the ground lug assembly. Tighten the outer nut against the middle nut without twisting the ground lug. Tighten securely.
- 6. Attach the red wire inside the feed through box to the feed through using the screw removed in step 4 and a star washer and flat washer supplied in kit.
- 7. Attach the feed through cover (31-50146-0-001) onto the feed through box. Secure the cover with the four screws located on top of the cover. Tighten screws with screwdriver.
- 8. Screw on one end of the twinax cable (66-50518-001) to the power verification meter (35-50425-0-001) connector labeled "From LFPS2." The connectors are keyed for proper orientation. Route the rest of the cable to where the RF generator was located.
- 9. For the latest RF generator (long rectangular enclosure), fasten the LFPS2 to the sterilizer using the same hardware used with the RF generator.
- 10. For the old RF generator (box type), remove the air duct above the control enclosure. The LFPS2 includes a bracket with mounting holes. Align the LFPS2 to the two outside mounting holes for RF generator that was removed. Make certain that the LFPS2 connectors are facing the front of the sterilizer, otherwise, remove the bracket from the LFPS2 by removing the 4 mounting screws on the bottom of the unit. Flip the bracket and remount it on to the LFPS2. The two mounting holes for the LFPS2 are the two outside holes which were used for the RF generator. They are right above the mounting holes for the air duct
- 11. Attach the control cable to the LFPS2 (40-50554-002). Secure the screws on the connector to the LFPS2 using a flat head screw driver.
- 12. Screw on the other end of the twinax cable (66-50518-001) to the LFPS2. Make certain that the key on the connector lines up with the LFPS2 connector.
- 13. Connect the IEC320 power cord to the LFPS2. (Use the power cord from the Bird Wattmeter.)

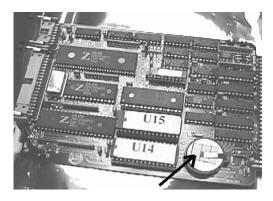
# Firmware Verification and Jumper Configuration

### \*\*\*STATIC SENSITIVE DEVICES PRESENT\*\*\*

Operators must be grounded at all times to prevent ESD damage to electronic assemblies. A wrist strap connected to the system chassis should be worn while handling ESD sensitive components. The system chassis must be "earth grounded" through the AC Line Cord plug to ensure proper ESD protection.

14. Ensure main power circuit breaker is in OFF position.

- 15. Remove the control enclosure rear panel to expose circuit cards.
- 16. Remove the existing microprocessor circuit card and place on a electrostatic controlled work area.
- 17. Verify the minimum firmware version on U14 and U15: 04-05526-6-601 for US domestic systems or 04-05524-3-6XX for international systems. If the firmware is an earlier version, update the firmware per TB115999.



- 18. Reinstall the microprocessor circuit board into the control enclosure and reconnect ribbon cables.
- 19. For Block 2 units make sure Jumper J1 from 04-01766-2-001 Distribution PWA has been removed or straddles over pin 1 as shown below for future use. The system will not operate correctly if this jumper is not positioned over 1 pin as shown (or completely removed.)



### **Install Safety Switch**

- 20. Follow all good safety practices. Ensure the work area is safe, and well lit.
- 21. Close the sterilizer door.
- 22. Remove the left side panel of the system.
- 23. Locate the Top Door Optical Sensor bracket. Locate and disconnect the Top Door Sensor harness connector, marked J44 from the main harness assembly.
- 24. Remove the Top Door Sensor bracket assembly(ASP P/N 31-02534-001) by removing the two, M4 x 100mm mounting screws from the guide rail.

25. From the LFPS2 KIT, STERRAD<sup>®</sup> 100S, USA (05-50559-0-002), Sensor/Safety switch assembly, Door, Top (03-50409-1-001), locate the bracket (31-50401-001) and the PWA, Sensor, Door (04-00975-001). Assemble the PWA on to the Bracket using two M3 x 6mm screws and flat washers supplied in the kit. Make sure that the mounting screws are centered on the mounting slots of the PWA, and it is in the proper location for the machine version (block 1.8 or 2.0) as depicted in figure 1.

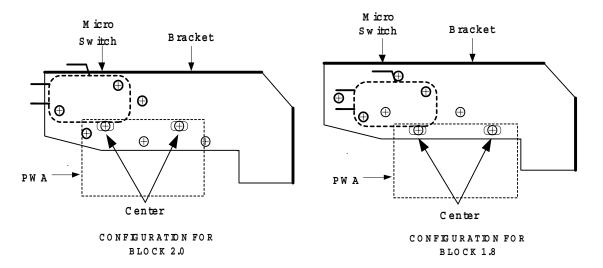


Figure 1

- 26. From Sensor/Safety switch assembly, Door, Top (03-050409-1-001), mount the Micro Switch (57-50410) on to the bracket using two M2.5 x 25mm screws supplied in the kit. Make sure the switch is mounted in the appropriate location for the machine version (Block 1.8 or 2.0). See figure 1.
- 27. Loosen the two M4 x 8mm mounting screws for the Door Flag (ASP P/N 31-01082-001), located at the bottom left of the door assembly.
- 28. Install the grommet shim, ASP P/N 63-01441-102 on to the top of the door flag. Position the grommet shim such that both ends of the door flag, and the grommet shim are even with one another. See figure 2.

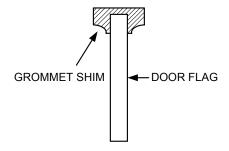


Figure 2

- 29. Mount the completed Sensor/Safety switch assembly loosely to the left guide rail using two M4 X100mm screws.
- 30. Position the bracket so that the door flag is centered inside the optical sensor, and clear of the path of the door. Align the bracket so that the end of the flag is not touching the back of the sensor body. Tighten the two M4 mounting screws. See figure 3..

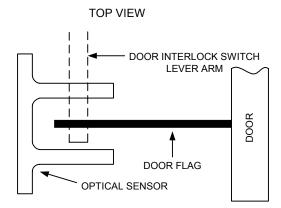


Figure 3

31. With the door still closed, slide the loosely positioned door flag upward between the optical sensor until the flag is contacting the interlock switch moment arm. Continue to slide the flag upward until an audible click from the switch is heard (switch engaged), and the moment arm of the switch is at the end of it's travel. Tighten the two M4 x 8mm screws. Ensure the flag is positioned perpendicular to the door in both axis, and that the flag is centered between the optical sensor. Readjust if necessary. See figure 4.

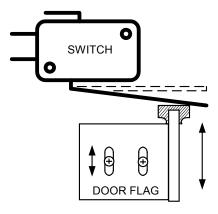
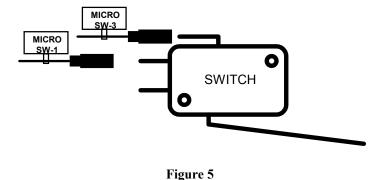


Figure 4

- 32. Open door. Remove grommet shim from the flag, and close door.
- 33. Using a DVM, check for continuity between the top contact (COM) and the second contact (N.O. 3) of the switch. Readjust the door flag on step 31, if there is no continuity between the contacts.
- 34. Operate the door and observe the travel of the flag. The flag should travel freely through its intended path with no obstruction. Readjust the door flag, and /or the bracket assembly as needed.
- 35. From the LFPS2 KIT, locate Harness assembly, RF control/safety (04-50408-0-001).
- 36. Connect J21 (DB9) to the control enclosure. Route harness with the main wire bundle from the control enclosure.
- 37. Route and tie-wrap the 180cm long, 2 conductor harness with quick connects marked with Micro SW-1 and SW-3, along the main wire bundle along the frame, and towards top door optical sensor.
- 38. Tie-wrap the harness marked Micro SW1 and SW-3 with the Top Door Sensor harness connector, marked J44 from the main harness assembly (ASP P/N 03-03251).
- 39. Connect J44 back to the optical PWA.
- 40. Connect the quick connect marked Micro SW-3 to the switch COM contact. See figure 5.
- 41. Connect the quick connect marked Micro SW-1 to the switch N.O.3 contact. See figure 5.



42. Check all connections. Secure all loose harnesses with tie-wraps.

### Verify LFPS2 system

43. Connect one end of the short (12") twinax cable (66-50520-001) to the power verification meter connector labeled "To Chamber." Attach the other end to the feed through box connector.

- 44. Connect the BNC to banana plug cable to the power verification box (BNC) and to a volt meter (banana). Make certain that the ground on the banana plug is inserted correctly into the low input on the volt meter.
- 45. Connect an IEC320 power cord to the power verification meter. Find an outlet to plug the power cord into. Verify that the power verification box has power (illuminated yellow LED). Allow the verification box to warm up for 5 minutes.
- 46. Turn the volt meter on and set to the DC voltage mode. Press and hold the red button. Verify that the volt meter reads 5.00±0.01 volts.
- 47. Install the service access key on ribbon connected to J2 of the microprocessor PWA and enable Autotest. (Refer to TS-50026-0-002 Service Access Key Autotest Guide for specific instructions) Set the Plasma time to 15.0 minutes. Select and run the RF/Leak test **without** injection.
- 48. When the plasma is on, verify that the voltmeter reading from the power verification meter is 3.20±0.16 volts.
- 49. At the end of the test, verify that the print-out shows power is 380-420 watts. Exit the Autotest function.
- 50. Turn off and remove the power verification meter along with the one foot long twinax cable.
- 51. Connect the twinax cable coming from the LFPS2 to the feed through box.
- 52. Re-install all panels except the rear control enclosure cover and the sterilizer lower rear panel.
- 53. Turn on the main breaker.
- 54. Measure and record on the fax back sheet the AC voltage between the electrode and chamber wall.

# **System Functional Verification**

Verify proper system function by performing a Product Certification and running a Test (empty) Cycle on either cell # 1, 2, 9, or 10; (note: these cells are the most challenging from an ISI algorithm point of view). Follow the procedure below to run a Test Cycle:

- 1. Install the service access key on ribbon connected to J2 of the microprocessor PWA.
- 2. Press **OPEN** and wait for door to open
- 3. Press **START** and **CANCEL** simultaneously to enter the edit mode.
- 4. Press **START** and **OPEN** simultaneously to enter the deep editor.
- 5. At the submenu, press **CANCEL** until it displays the Test Cycle.
- 6. Press **OPEN** to change the default setting from **DISABLED** to **ENABLED**.

- 7. Press **CLOSE** to accept and exit the Test Cycle.
- 8. Press **START** and **OPEN** to exit the deep editor submenu.
- 9. Press **START** and **CANCEL** to exit Edit mode.
- 10. Remove the service access key and re-install the rear cover on the control enclosure. (Do not turn off the power to the unit when removing the service access key or the test cycle will not be enabled.)
- 11. Insert a new cassette and press **START** to start a cycle.
- 12. Once the cycle is completed cycle data and seal height adjustment data is printed. This printout shows the actual injection pressure at 5 second intervals between 0 and 70 seconds.
- 13. Verify that the test cycle data is printed in red and is labeled with the "For Testing Purposes Only" header. If not, perform a master reset to ensure that the system's memory is properly cleared.
- 14. The test cycle defaults back to a normal cycle after one test. If you need to run a second test, repeat steps 1 through 13 in this section.
- 15. Press START and run a complete cycle.
- 16. Ensure that all cycle parameters comply with functional specifications.
- 17. Return the Fax Back sheet to the number listed on the sheet.

Technical Bulletin Number: TB11	6099 Date: 4/26/02			
	Mandatory Mandatory Next Call As Required			
Technical Bulletin Title: LFPS2 ir	n STERRAD <sup>®</sup> 100S Systems			
Product(s) Covered:				
Part Numbers: 05-50559-0-002  Country Location:				
Hospital Name				
Software Version:				
AC Voltage measured between electrode and ch  Completion Date:  Completed By:	amber wall:			
Mail or Fax to:				

Advanced Sterilization Products Attention – Customer Support 33 Technology Irvine, CA 92618 USA FAX 949.450.6800

<b>Technical</b> Bulletin Number: TB117299 Date: 6/18/02			
Technical Bulletin Category: ☐ Mandatory ☐ Mandatory Next Call ☐ As Required			
Technical Bulletin Title: STERRAD® 100S Software Upgrade			
Product(s) Covered:10050			
Originator, If this bulletin is Mandatory or Mandatory Next Call, please add all STERRAD $^{\otimes}$ or ASP AER Models affected to the field below.			
00-10101-0-001, 00-10101-0-002, 00-10101-1-001, 00-10101-1-002. 00-10101-(2 through 7)-001			

Part Numbers: 04-05524-4-6XX and 04-05526-7-601

Technical Specialist: Tim Weidinger Phone: 949 789-3872

CO Reference: 07202-3 S/N Breakpoint 026817

Approvals-Must Be Hand Signed						
Originator	Date	Tech. Support		Date	Field Service	Date
T. Weidinger	6/18/02	N/A			T. Kijanka	6/18/02
Depot	Date	Supply Chain		Date	Regulatory	Date
A. Singh	6/19/02	T. Henderson		6/21/02	N. Bennington	6/19/02
Other	Date	Other		Date	Other	Date
Released	E-mail	Internet File			Bulletin Distribution	
		To Biomeds? Yes ⊠ No □				
			To International Affiliates Ye		ational Affiliates Yes 🛛 🛚 N	lo 🗌

# **Special Tools Required**

- Electrostatic Discharge Mat with wrist grounding strap
- EPROM Extractor
- Digital Volt Meter (Fluke 87, 97, 99, or equivalent)
- Service Access Key (ASP P/N 04-09071-0-001)
- Harness 04-00323-0-001 for Block 1.8 systems upgraded to 100S prior to 2001

### **Problem**

- 1. In Autotest, systems with LFPS2 plasma generators were not able to reliably light plasma if the peroxide injection option was enabled.
- 2. In Autotest Analog test, data shown on LCD were not always accurate due to potential overflow conditions.
- 3. Autotest did not have a separate Vent Valve test.
- 4. The Autotest Leakback test could show erroneous data in extreme conditions due to data format in software.
- 5. In Idle condition, some LCD displays could show erroneous data.
- 6. LCD and printer messages directed the customer to SEE OP MANUAL while user documentation is titled User's Manual.
- 7. LCD and printer messages directed the customer to CONTACT TECHNICAL SERVICE (LCD) or CONTACT ASP TECHNICAL SERVICE (printer). This caused some confusion for our customers because the department handling these calls is titled Customer Support.
- 8. Cycle cancellation for VACUUM SYSTEM INTERRUPTED during plasma stage printed incorrect pressure on the printout for that plasma stage.
- 9. When exiting the Autotest function, the system printed the summary printout (report of every test regardless of whether every test was run.)

### Solution

- 1. Two minute vent was added to the Autotest VACRF test performed with peroxide injection, following the 6 minute injection period, prior to pump down to plasma pressure and light plasma.
- 2. Fix overflow problem in Autotest Analog test

- 3. Added new Vent Valve test to Throttle/Heater test suite (follows the Oil Switch test) in embedded Autotest.
- 4. Changed types of variables in the Autotest Leakback test from unsigned integer to unsigned long to prevent erroneous reading.
- 5. Enhanced software masking of noise generated display anomalies by re-writing display at 100 msec intervals in Idle as well as during the cycle.
- 6. Changed messages containing "SEE OP MANUAL" to "SEE USER GUIDE".
- 7. Per Customer Support request, changed messages containing "TECHNICAL SERVICE" to "CUSTOMER SUPPORT".
- 8. Corrected software to print the current pressure when canceling for VACUUM SYSTEM INTERRUPTED.
- 9. Turned off the Autotest summary report for customer software versions. The system will now print the tests performed.

# Parts Changes/Update Information

Part Number	Replaced by	Description
04-05524-3-60X	04-05524-4-60X	Firmware, 10101, International
04-05526-6-601	04-05526-7-601	Firmware, 10101, USA
05-04420-6-XXX	05-04420-7-XXX	Kit, Upgrade, 10101, B1.8 International
05-04631-7-XXX	05-04631-8-XXX	Kit, Upgrade, 10101, B2.0 International
05-06420-7-XXX	05-06420-8-XXX	Configuration Kit, English, 10101, International
05-06421-7-XXX	05-06421-8-XXX	Configuration Kit, Spanish, 10101, International
05-06422-7-XXX	05-06422-8-XXX	Configuration Kit, Italian, 10101, International
05-06423-7-XXX	05-06423-8-XXX	Configuration Kit, French, 10101, International
05-06424-7-XXX	05-06424-8-XXX	Configuration Kit, German, 10101, International
05-06425-7-XXX	05-06425-8-XXX	Configuration Kit, Swedish, 10101, International
05-06426-7-XXX	05-06426-8-XXX	Configuration Kit, Finnish, 10101, International
05-06427-7-XXX	05-06427-8-XXX	Configuration Kit, Portuguese, 10101, International
05-06428-7-XXX	05-06428-8-XXX	Configuration Kit, Dutch, 10101, International
05-06429-6-XXX	05-06429-7-XXX	Configuration Kit, Japanese, 10101, International
05-06430-7-XXX	05-06430-8-XXX	Configuration Kit, Hungarian, 10101, International
05-09786-3-XXX	05-09786-4-XXX	Configuration Kit, 10101, USA
05-09936-4-XXX	05-09936-5-XXX	Kit, Upgrade 10101, USA

### Overview

- Confirm that unit hardware has already been upgraded to 100S.
- (International) Order applicable EPROMS through your Customer Support Representative (P/N 04-05524-4-60X). See table below for P/N. They are free of charge.

04-05524-4-601	International English
04-05524-4-602	German
04-05524-4-603	French
04-05524-4-604	Japanese
04-05524-4-605	Italian
04-05524-4-606	Spanish
04-05524-4-607	Swedish
04-05524-4-608	Finnish
04-05524-4-609	Greek

- (Domestic) Order EPROMS through normal ordering methods (P/N 04-05526-7-601)
- Replace firmware and configure unit.
- Complete notification form and fax to (949) 450-6852 (001.949.450.6852)

## **Procedure**

### **Obtain System Variable Information (Edit Mode)**

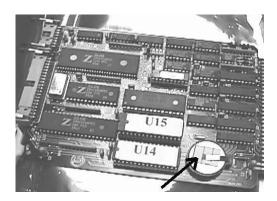
- 1. Locate printout from last cycle. Note the Total Machine Cycles and System Serial Number.
- 2. Make sure the door is open when performing this procedure. Enter the Edit Mode by simultaneously pressing START and CANCEL The current date is displayed on the LCD.
- 3. Simultaneously press START and OPEN to enter the deep edit mode. Press the CANCEL button twice to access the number of cycles to next PM interval. Record the number of cycles to next PM.

### Firmware Installation and Jumper Configuration

#### \*\*\*STATIC SENSITIVE DEVICES PRESENT\*\*\*

Operators must be grounded at all times to prevent ESD damage to electronic assemblies. A wrist strap connected to the system chassis should be worn while handling ESD sensitive components. The system chassis must be "earth grounded" through the AC Line Cord plug to ensure proper ESD protection.

- 4. Turn main power circuit breaker to OFF position.
- 5. Remove rear panel.
- 6. Remove the control enclosure rear panel to expose circuit cards.
- 7. Remove the existing microprocessor circuit card and place on a electrostatic controlled work area.
- 8. Remove the existing firmware and replace it with applicable firmware (04-05524-4-60X or 04-05526-7-601). Note the checksums listed on the EPROMs. Pay particular attention to the orientation of the EPROMs during insertion into their IC sockets. Additionally, exercise care to ensure that the EPROM pins are not bent, broken, or otherwise damaged during insertion.



- 9. Reinstall the microprocessor circuit board into the control enclosure.
- 10. For Block 2 units remove Jumper J1 from 04-01766-2-001 Distribution PWA inside the control enclosure and straddle over 1 pin as shown below for future use (or completely removed.) The system will not operate correctly if this jumper is positioned over both pins.



11. Turn the main power circuit breaker ON.

#### Perform a master reset.

12. Defeat the control enclosure safety interlock switch by applying power to the enclosure while simultaneously pressing and holding CANCEL until two beeps are heard.

Note: <u>The following steps must be followed in sequence.</u> If they are performed out of order, the system may behave unpredictably. Specifically, Total Machine Cycles <u>must</u> be set to zero FIRST, and NOT reset to zero after other parameters have been set.

- 13. Make sure that the door is open first. Enter the edit mode by simultaneously pressing the START and CANCEL buttons. The system displays the current date information.
- 14. While in the edit mode, simultaneously press START and OPEN for five seconds, the system displays the Total Machine Cycles.
- 15. The total machine cycles menu looks like this:

TOTAL MACH. CYCLES XXXXX OPEN(CHNG) - CLOSE(ACCEPT)

XXXXX represents the total machine cycles run.

## **Set Total Machine Cycles to Zero**

Note: The total machine cycles MUST be reset to ZERO, even if the screen already displays zero. The action of setting total machine cycles to zero causes the software to reset essential variables and process parameters normally protected from reset at power-up.

16. The cursor should be blinking under the right most digit of the total machine cycle count. Press CLOSE 4 times to move the cursor to the left. Press OPEN until the system resets the total machine cycles to 0. Performing this step also resets the serial number.

After resetting, the total machine cycles menu looks like this:

TOTAL MACH. CYCLES 0
OPEN(CHNG) - CLOSE(ACCEPT)

Note: The "Set Total Machine Cycles to Zero" steps MUST be performed prior to setting the total machine cycles since software function is not reliable until this procedure is performed to zero the memory.

### **Setting the Total Machine Cycles**

- 17. Press OPEN enough times to change the right most digit of the machine cycles back to the number noted in Step 1.
- 18. Press CLOSE to move the cursor to the left. Press OPEN to set the next digit. Continue pressing CLOSE to move the cursor and OPEN to set the digits to correspond to the total machine cycles noted in Step 1.
- 19. Press CANCEL to change the fields. The PM Log is displayed.

## **Setting PM Log**

The display looks like the following example:

P.M. N: NEXT PM XXX
OPEN (reset) - CANCEL (next)

Note: The cursor flashes on the N/Y field. The NEXT PM field displays the total remaining cycles before the PM is due. Press CANCEL to move to the next field.

- 20. Check the PM log to ensure that the system will not become due for PM within 100 cycles. If the system is within 100 cycles of a PM, perform the PM per the service manual and reset the log appropriately.
- 21. Press CANCEL to change the fields. The Serial Number field is displayed.

## **Setting the Serial Number**

The serial number menu looks like this:

SERIAL NUMBER XXXXXX
OPEN(CHNG) - CLOSE(ACCEPT)

XXXXXX represents the machine serial number; it can be any number from 0 to 999999.

- 22. Press OPEN to change the right most digit to match the serial number recorded in step 1.
- 23. Press CLOSE to move the cursor to the left. Press OPEN to set the second digit. Repeat the process to complete setting the serial number.
- 24. When you have set the serial number, press CLOSE so that you do not accidentally change the number.
- 25. Press CANCEL to move sequentially through the available menus.

### **Setting the Clock Mode**

26. Simultaneously press START and OPEN to exit the deep editor. Press CANCEL twice to display the following

CLOCK MODE XX
OPEN(chng)-CLOSE(accept)

XX is the mode of the clock (12 hour time or 24 hour time).

- 27. Press OPEN to toggle the clock mode to a desired setting. This setting affects all printed time notations and the time display in the editor.
- 28. Set the time and date variables to the desired values.
- 29. (International only) Press CANCEL to change the fields. The Default Cycle is displayed. Press OPEN to toggle the default cycle to the desired setting.
- 30. Press START and CANCEL to exit the edit mode. The printer will print: (Date) MM/DD/YY (Time) HH:MM:SS

SERIAL NUMBER = (XXXXXX)

Language and Checksums

(Microprocessor PWA P/N) 04-0552X-X-00X (S/W date) MM-DD-YY

31. Verify the last two sets of checksums on the printout match the values recorded in step 8.

# **System Functional Verification**

Verify proper system function by performing a Product Certification and running a Test (empty) cycle. Follow the procedure below to run a Test Cycle:

- 1. Install Service Access Key on ribbon connector (04-00323-0-001) attached to J2 connector on microprocessor PWA.
- 2. At the main screen, press **START** and **CANCEL** buttons simultaneously to enter edit mode.
- 3. Press **START** and **OPEN** buttons simultaneously to enter sub-menu screen.
- 4. While in sub-menu screen, press **CANCEL** button 10 times until Test Cycle screen is displayed.
- 5. Press **OPEN** button to change the default setting from **DISABLED** to **ENABLED**
- 6. Press **CLOSE** to accept and exit Test Cycle screen.
- 7. Press **OPEN** and **START** buttons to exit sub-menu screen
- 8. Press **START** and **CANCEL** to exit edit screen.

- 9. Remove the Service Access Key from the ribbon cable.
- 10. Insert a new cassette and press **START** button to start cycle.
- 11. Once the cycle is completed the printout will print cycle data and seal height adjust data which shows the actual injection pressure at 5 second intervals between 0 and 70 seconds
- 12. The Test cycle will default back to normal cycle after one test. Repeat System Function Verification steps 1-9 to re-enable the test cycle if you need to run a second test.
- 13. Ensure that all cycle parameters comply with functional specifications.
- 14. Complete the Completion Notification sheet and attach the print-out in the space provided. Fax or mail to the number/address specified on the sheet.

Technical Bulletin Number: TB117299	Date: 6/18/02			
Technical Bulletin Category:    Mandatory				
Technical Bulletin Title: STERRAD®	100S Software Upgrade			
Product(s) Covered: ☐10050 ☐10100 ☑10101 ☐10102 ☐10200 ☐10217 ☐2030X ☐				
Country Location:				
Hospital Name and Address:	Attach editor checksum printout here.			
System Serial Number:				
International Software Version:	Domestic Software Version:			
04-05524-4- <u>60</u>	04-05526-7-601			
Completion Date: Completed By:				

Mail or Fax to:
Advanced Sterilization Products
Attention – Customer Support
33 Technology
Irvine, CA 92618 USA

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